

**UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF MICHIGAN  
SOUTHERN DIVISION**

LAYLA FAKHR EL-DIN EL-SAWY and  
EGYPTIAN EUROPEAN  
PHARMACEUTICAL INDUSTRY,  
an Egyptian corporation,

Case No.

Hon.

Plaintiffs,

v.

REGENTS OF THE UNIVERSITY  
OF MICHIGAN, a non-profit educational  
institution of the State of Michigan, and  
MARK L. DAY,

Defendants.

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**COMPLAINT**

Plaintiffs Layla Fakhr El-Din El-Sawy and Egyptian European  
Pharmaceutical Industry, by their counsel, The Miller Law Firm, P.C., state as

follows for their Complaint against Defendants, Regents of the University of Michigan and Mark L. Day:

### **JURISDICTION AND PARTIES**

1. Plaintiff Egyptian European Pharmaceutical Industry (“EEPI”) is an Egyptian corporation with its principal place of business in Alexandria, the Arab Republic of Egypt (“Egypt”).

2. Plaintiff Layla Fakhr El-Din El-Sawy (“Ms. El-Sawy”) is a resident of Alexandria, Egypt and a citizen of Egypt and of the United States.

3. Defendant Regents of the University of Michigan (“U-M”) is a non-profit educational institution of the State of Michigan.

4. Defendant Mark L. Day (“Day”) is a resident of Livingston County, State of Michigan.

5. Jurisdiction is appropriate pursuant to 28 U.S.C. § 1332 as there is complete diversity of citizenship between Plaintiffs and Defendants and the amount in controversy exceeds \$75,000, exclusive of interest, costs, and attorneys’ fees. Jurisdiction is further appropriate under 28 U.S.C. § 1331, as this Complaint presents a federal question pursuant to 48 U.S.C. § 1983. Jurisdiction is therefore available over the supplemental state law claims pursuant to 28 U.S.C. § 1367.

6. The acts and events giving rise to this lawsuit occurred in Washtenaw County, Michigan, which is located in the Southern Division of the Eastern District

of Michigan. Venue is therefore proper in this Court pursuant to 28 USC § 1391(b)(2).

### **INTRODUCTION**

7. EEPI is an Egyptian company that researches, develops, manufactures, markets, distributes, and exports pharmaceutical products through a global network of partnerships. It is a subsidiary of Pharco Pharmaceuticals (“Pharco”), which is also an Egyptian company.

8. EEPI scientists discovered that a wild plant endemic to the Nile Valley of Egypt was a potential source of an anti-cancer agent.

9. U-M and Day, a U-M scientist who operates the eponymous Day Laboratory within the U-M Department of Urology, held themselves out to EEPI as possessing all the capabilities required to perform the scientific studies needed for the U.S. Government to approve a potential new drug.

10. Accordingly, in 2012, EEPI engaged U-M to conduct a modest preliminary investigation of that discovery and entered into a contract for those purposes. The cost of this initial, exploratory investigation was to be less than \$100,000.00. EEPI’s long-term objective, to develop a drug that could be marketed globally, including in the United States, was known and understood by U-M and Day from the beginning of the research project.

11. U-M and Day encouraged EEPI to believe that their work was yielding promising results and persuaded EEPI to continue funding the research project. EEPI ultimately paid U-M more than \$2,300,000 under both the original 2012 contract and a later contract between EEPI and U-M executed in 2015. The 2015 contract was for preclinical research to determine whether the potential drug was safe and effective enough to proceed with clinical trials on human subjects as well as a final report on its findings.

12. The final report was the critical deliverable under the 2015 contract, upon which U-M and Day understood that EEPI would rely to proceed to the clinical testing phase, obtain financing, apply for patent protection, and publish scientific papers announcing the potential new drug to the world.

13. Ms. El-Sawy was employed by U-M in the Day Laboratory in support of the work to be conducted pursuant to the contractual relationship between U-M and EEPI.

14. In the spring of 2017, Day advised EEPI that the preclinical research project, which was scheduled to be completed by the end of June 2017, would have to be extended and additional funding provided. EEPI responded to U-M and Day that it would not agree to fund additional research until it saw the results of the then-current preclinical project in the form of the final report.

15. In April 2017, U-M and Day presented a four-page memorandum, accompanied by a PowerPoint presentation, which they represented as the long-awaited final report. It was immediately obvious that this so-called “final report” was a confused and shoddy effort unworthy of a university that holds itself out as a first-class medical research establishment.

16. Upon further study, the “final report” revealed that the preclinical study had been conducted so poorly and outside of scientific norms that its results were effectively meaningless and that its optimistic conclusions were completely unsupported. EEPI received no meaningful scientific value in return for its multimillion-dollar investment. The final report neither established the potential new drug’s safety and effectiveness nor its lack thereof.

17. Worse, upon closer examination it became apparent that the results of at least one experiment cited in the “final report” had been falsified, apparently to justify Day’s excessive expenses and to position the experiment’s results as a discovery constituting the intellectual property of Day and/or U-M.

18. The scope of work that U-M and Day proposed for the preclinical study required by the 2015 contract clearly contemplated that the study would be “preclinical” in nature, meaning that it would be designed and carried out in a manner consistent with EEPI’s objective of proceeding to clinical trials and, if the potential new drug survived that test, to the marketing and distribution of the new

drug. Instead, the “final report” established that the study was designed and carried out in near-total disregard of the legal and scientific requirements for preclinical research, and with such a low standard of scientific skill and integrity as to be essentially valueless.

19. Day’s and U-M’s misconduct regarding the EEPI research included the discriminatory mistreatment of Ms. El-Sawy. Day, in his capacity as an employee of U-M (and thereby in his capacity as a government employee) subjected Ms. El-Sawy, an Arab and Muslim woman of Egyptian heritage, to relentless harassment and discrimination on account of her gender, race, religion, ethnicity, national origin, and naturalized citizenship.

20. Day exhibited this racist, misogynistic, xenophobic, and illegal behavior in at least three ways. First, Day was repeatedly, specifically, and abusively profane to Ms. El-Sawy, even after she informed Day of the offense this was causing her specifically as a Muslim woman. Day’s abusive behavior, which was later acknowledged by him and U-M, eventually escalated to stalking. Day did not exhibit the same behavior towards white people, Americans, or men who worked in the laboratory.

21. Second, Day repeatedly made clear to Ms. El-Sawy that her status in his laboratory at U-M was inferior to his *specifically because he was a white man entitled to act with impunity*. This is not conjecture: on at least two separate

occasions, Day specifically informed Ms. El-Sawy that, as a white American man, he could do whatever he wanted to her, an Arab, Egyptian, Muslim woman, and she could do nothing to stop him.

22. Third, Day supported the behavior of his wife, also employed by U-M in the same laboratory, who continuously used her position to denigrate Ms. El-Sawy's religion and attempt to convert her from Islam to Christianity.

23. Day's abusive and discriminatory behavior was directed specifically at Ms. El-Sawy not in spite of her particular susceptibility as an Arab, Egyptian, Muslim woman, but *because* of that status.

24. After Plaintiffs analyzed the purported final report from U-M and Day. EEPI raised the report's deficiencies and U-M's and Day's failure to perform under the parties' agreements with U-M.

25. When he learned of EEPI's response to the purported final report, and acting out of illegal and unconstitutional animus, Day escalated his abuse and discriminatory behavior against Ms. El-Sawy. Day targeted Ms. El-Sawy in an outrageous and relentless campaign of abusive and discriminatory conduct, including electronic stalking and open threats to attack her reputation with the intent of causing permanent harm to her professional career. Defendants have admitted Day's abusive behavior towards Ms. El-Sawy and U-M's responsibility.

26. Defendants' abusive, discriminatory, and unconstitutional behavior has caused substantial physical, emotional, mental, and professional damage to Ms. El-Sawy.

27. Defendants' actions have also caused substantial economic damage to EEPI.

### **FACTUAL BACKGROUND**

#### *The Contractual Relationship Among the Parties*

28. The flowering plant *Ambrosia maritima* ("A. maritima") is a member of the family Asteraceae that grows wild along the banks of the Nile River in Egypt. Since before recorded history, *A. maritima* has been used in traditional medicine to treat a variety of illnesses, including cancer.

29. Dr. Mohamed Fakhr El-Din El-Sawy ("Mohamed El-Sawy"), a citizen of Egypt residing in Alexandria, Egypt, is a biologist who primarily studies medicinal plants native to Egypt. Mohamed El-Sawy has studied the medicinal properties of *A. maritima* since the 1960s. Mohamed El-Sawy originally discovered the properties of *A. maritima* that led to the partnership between EEPI and U-M.

30. Ms. El-Sawy, who also resides in Alexandria, Egypt, is a biologist engaged primarily in cancer research. Ms. El-Sawy is Mohamed El-Sawy's daughter.

31. Ms. El-Sawy and Mohammed El-Sawy have collaborated on their research into, and development of, the medicinal uses for *A. maritima* for years,



beginning long before the EEPI/U-M partnership was even contemplated. *A. maritima* represents their lives' work.

32. In and before 2012, Ms. El-Sawy was employed by EEPI as a research scientist. In that capacity she researched the potential use of chemical compounds derived from *A. maritima* as anti-tumor agents in the treatment of cancer. Ms. El-Sawy is currently a senior scientist with EEPI in Alexandria.

33. Ms. El-Sawy became acquainted with Day in 2010 while she was studying in the United States, during which time she volunteered in Day's laboratory at U-M. In particular, Day expressed interest in the research conducted by Mohamed El-Sawy and Ms. El-Sawy for EEPI concerning *A. maritima* as a potential anti-cancer agent.

34. In April 2012, Ms. El-Sawy was traveling to the United States and took an opportunity to visit Day's laboratory. Day was aware of the relationship between Ms. El-Sawy and EEPI and Pharco, and he told her that he was looking for a sponsor for a research project, called ADAM15, for the treatment of bladder cancer.

35. When Ms. El-Sawy returned to Egypt, she discussed the ADAM15 project with Dr. Sherine Helmy of EEPI/Pharco. Dr. Helmy agreed to sponsor that project through Pharco/EEPI. This project did not prove successful. However, when it ended, Ms. El-Sawy believed there was an opportunity to continue the

collaboration between U-M and Day and Pharco/EEPI, now with the *A. maritima* project.

36. Ms. El-Sawy introduced Day to Mohamed El-Sawy, Dr. Helmy, and other senior management at EEPI for the purpose of discussing EEPI's *A. maritima* research and to explore the possibility of U-M conducting further investigation on EEPI's behalf. Day traveled to Egypt for this purpose.

37. In particular, the discussion centered on potential research by Day and U-M to determine whether *A. maritima* could be a source of chemical compounds meriting preclinical research as possible anti-cancer agents. EEPI and Day also discussed the idea of Ms. El-Sawy's participation in the *A. maritima* research, that would include training in relevant preclinical research by Day.

38. EEPI and U-M entered into a contract dated June 14, 2012 for a preliminary study of *A. maritima* (the "First Research Agreement"). The First Research Agreement contemplated a one-year study to be conducted at EEPI's expense as the "sponsor." The cost of the study as provided in the First Research Agreement was "not to exceed the sum of Dollars [sic] (\$97,118.)." The scope of the project contemplated by the First Research Agreement (the "Project") was described in Exhibit A to the First Research Agreement. Defendants are in possession of a copy of the First Research Agreement.

39. Article 7 of the First Research Agreement reserved to EEPI, as the Sponsor, “the right to use data, information, and reports that are prepared by the University in the performance of the Project.”

40. The First Research Agreement expired according to its terms on July 1, 2013. Over the course of July 2013, EEPI and U-M reviewed the results of the Project to that point and found them to be encouraging. Accordingly, they entered into an amendment (“Amendment No. 1”) to the First Research Agreement, extending its term through June 30, 2016. Defendants are in possession of a copy of Amendment No. 1 to the First Research Agreement.

41. Amendment No. 1 provided for a “fixed price” of \$664,882.00 to be paid in quarterly installments. It incorporated a Memorandum of Understanding entitled “GU Cancer Research and Training Collaboration between European Egyptian Pharmaceutical Industries a subsidiary of Pharco Group and” Defendant, “Dr. Mark L. Day at the University of Michigan” (the “MOU”) that set forth an expanded scope of work of the Project. The MOU recited: “(EEPI) has recently concluded meetings with [Day] to initiate a research collaboration focused on the development of prostate and bladder cancer therapeutics.” The MOU also contemplated that Day would continue to train Ms. El-Sawy and assist her in establishing a genitourinary cancer research program at EEPI.

42. The MOU refers to *A. maritima* as “FXY204.” The MOU detailed a five-stage study to be completed in two years.

43. On July 9, 2013, Pharco Corporation and EEPI separately entered into a one-page “Consulting Agreement” with Day in his individual capacity (the “Day Consulting Agreement”). The Day Consulting Agreement was entirely independent from EEPI’s arrangement with U-M. Day agreed to, *inter alia*, “continue to advise Dr. Layla El-Sawy ... in establishing a bladder cancer research program at EEPI,” including certain training of Ms. El-Sawy. It also required Day to advise and consult on other related matters. Day was required to “generate 4 quarterly reports for EEPI detailing developments on all 4 topics.” In exchange, EEPI was to pay Day a once-monthly sum of \$3,500 “by check mailed to his home.” Day is in possession of a copy of the Day Consulting Agreement.

44. The Day Consulting Agreement was for an initial term of one-year, to be reviewed for potential extension or renegotiation on June 30, 2014. The Day Consulting Agreement was extended by agreement of the parties three times, each for a period of one year: on July 15, 2014, November 1, 2015, and August 9, 2016.

45. The Day Consulting Agreement ended on August 9, 2017. It was not renewed.

46. Under the Day Consulting Agreement, as extended, EEPI has paid Day fees amounting to \$174,500.

47. In or about June 2015, shortly before the end of “year 2” under the MOU, EEPI and U-M determined that the progress of the Project was sufficient to enter a “preclinical” phase, that is, it should be conducted in a manner consistent with the objective of developing a drug that could proceed to clinical trials using human subjects.

48. Accordingly, EEPI and U-M entered into a new contract dated July 1, 2015 (the “Second Research Agreement”). The term of the Second Research Agreement was two years, expiring on July 1, 2017. The total cost to EEPI as Sponsor was not to exceed \$1,515,032. Defendants are in possession of a copy of the Second Research Agreement.

49. Day was named in Article 1.1 of the Second Research Agreement as the “Principal Investigator” responsible for directing the Project. The scope of the Project was redefined in Appendix A to the Second Research Agreement (“Appendix A”), entitled “Preclinical development of the FXY anti-cancer agent.”

50. Throughout the discussions between EEPI and U-M leading to the First Research Agreement, the First Amendment, and the Second Research Agreement, U-M held itself out as first-class medical research university knowledgeable, skilled, and experienced in all aspects of the conduct of biomedical research and possessing all of the personnel and facilities necessary to conduct such research, including

preclinical research, in compliance with applicable practices, standards, laws, and regulations.

51. Throughout the discussions between EEPI and U-M leading to the First Research Agreement, the First Amendment, and the Second Research Agreement, U-M and Day held Day out as an experienced medical research scientist possessing the knowledge, skills, and experience necessary to act as a principal investigator in charge of a biomedical research project, including preclinical research, complying with applicable practices, standards, laws, and regulations.

52. The principal reason for the early termination of the First Research Agreement and execution of the Second Research Agreement was that U-M and Day represented to EEPI that the results achieved under the First Research Agreement were by mid-2015 sufficiently promising to justify moving from the Investigative Phase to a preclinical phase of investigation to be governed by the Second Research Agreement (the “Preclinical Phase”).

53. The provisions of the Second Research Agreement reflect the parties’ mutual understanding that the Preclinical Phase was in the nature of a preclinical study. *In vivo* studies using animal test systems, as in the Preclinical Phase, are not normally done in preliminary investigative studies, but are typical of preclinical investigations.

54. Altogether, according to the terms of the First Research Agreement, the Second Research Agreement, and the Amendments thereto, EEPI paid U-M a total of \$2,180,209.00.

55. On August 22, 2017, after all the relevant contracts had terminated, Day approached Dr. Molokhia of EEPI and Parco seeking an increase in the project's budget for the coming years.

56. Dr. Molokhia responded to Day's request by stating that such an increase could only be approved subject to certain conditions. These conditions were all related to Day's failure to make certain reports required by the Operative Agreements from the beginning of the project. These conditions included that Day and U-M (1) comply with their pre-existing obligation to provide the full report on their previous projects; (2) provide a detailed budget with justifications for the requested changes; and (3) make a clear statement as to why Day and U-M failed to fully perform certain pre-clinical testing.

*The Objective: FDA Approval of a New Cancer Treatment Drug*

57. Throughout the discussions between EEPI and U-M leading to the First Research Agreement, the First Amendment, and the Second Research Agreement, U-M and Day knew and understood that EEPI's objective was to develop a cancer drug using compounds derived from *A. maritima* capable of being marketed and sold

in the United States. EEPI spent considerable amounts of money in pursuit of such development for marketing and sale in the United States.

58. In order to market and sell a new drug in the United States, the drug must first be approved by the U.S. Food and Drug Administration (the “FDA”).

59. To obtain FDA approval, a new drug must first be investigated in a nonclinical study, also known as a “preclinical study,” conducted using “good laboratory practices” (“GLP”) pursuant to federal regulations located at 21 CFR Part 58.1. Typically, a preclinical study of a potential new drug is preceded by a preliminary investigation to determine if the compound being studied shows sufficient promise to justify the time and expense required for a full-blown preclinical study.

60. The purpose of the First Research Agreement was to conduct a preliminary investigation (the “Investigative Phase”) to determine whether a preclinical study of compounds derived from *A. maritima* was justified.

61. In their discussions leading to the Second Research Agreement, U-M, Day, and EEPI used the term “preclinical study” to mean a study that, if successful, would meet the scientific and legal requirements to allow EEPI to proceed with a clinical study of the FXY anti-cancer agent using human subjects.

62. Throughout all of the discussions between EEPI and U-M leading the termination of the First Research Agreement and execution of the Second Research



Agreement, U-M and Day knew and understood that EEPI was relying on U-M and Day to advise EEPI whether the results of the investigation conducted under the First Research Agreement were promising enough to justify moving to a preclinical investigation.

*Day's Unconstitutional Racial, Religious, National Origin, Alienage,  
and Gender Discrimination Against Layla El-Sawy*

63. Ms. El-Sawy had worked on *A. maritima* for more than ten years before she came to U-M to participate in the collaborative project with Day. The connection between EEPI, on the one hand, and U-M and Day, on the other, was originally arranged by her.

64. Ms. El-Sawy quickly came to regret the connection. Over the course of their professional relationship and after Ms. El-Sawy left U-M, Day engaged in a cruel, vicious, and discriminatory campaign to demean Ms. El-Sawy in ways plainly motivated by his animus and contempt for her as a Muslim, an Egyptian, an Arab, a woman, and a naturalized citizen.

65. The clearest instance of such animus came from Day's efforts to assert his authority at U-M leading the Day Laboratory over Ms. El-Sawy. On these occasions, Day would make clear what he saw as the source of his power: not his position at U-M, but how his status as a white, male, native-born American placed him in a position atop society. Thus, on one occasion, Day told Ms. El-Sawy, "I am a white guy in the United States and I can do whatever the hell I want and nobody

will believe you.” On another occasion, he told her: “Everyone needs to understand that I am a Western man and you can’t touch me.” Day regularly acted on this perceived power to degrade Ms. El-Sawy with impunity.

66. Another incident occurred on October 11 and 12, 2015, after Day hired a young man to work in his laboratory at U-M as a laboratory technician. Day wanted that man to attend a laboratory presentation that Day and Ms. El-Sawy were to give to Dr. Molokhia on the progress of the research, and Ms. El-Sawy requested that he not be there. Ms. El-Sawy was concerned that because the relevant patent was yet un-published, the new employee’s presence would inform him about confidential and valuable intellectual property rights, and she rightly acted to protect her sponsor, EEPI. In response, Day yelled at her that, “What I say and what I demand goes! I am the boss, and you are not.” He then mocked Ms. El-Sawy, saying, “Would you like an honorary Ph.D.?” then laughed at her. When Ms. El-Sawy walked away, he followed her and yelled at her, in front of a colleague, to “take the f\*\*\*ing factor and go away! Get out or else I will call the university police and they will take you out!”<sup>1</sup> Ms. El-Sawy responded that his language was inappropriate and unacceptable. After the meeting took place, Day summoned Ms. El-Sawy in his office and yelled, “Don’t you ever challenge me! I am the boss here, and what I say goes.”

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<sup>1</sup> The “factor” referred to an investigational new drug that Ms. El-Sawy was researching at the time.

67. Ms. El-Sawy reported these incidents to Dr. Abdulla Molokhia, EEPI's Head of Research and an executive at EEPI's parent company, Pharco, contemporaneously.

68. Many other incidents were connected to Day's use of profane language, to which Ms. El-Sawy, as a Muslim woman, was uniquely, particularly sensitive. She made this clear to Day over and over again.

69. On multiple occasions, Ms. El-Sawy explained to Day her particular sensitivity and the religious and cultural basis for her offense. Day refused to moderate his language. Instead, he accelerated the profanity directed at Ms. El-Sawy. Day did not use similar language with white, male Americans in the laboratory.

70. Perhaps Day's most disturbing act was his facilitation of attempts to proselytize Ms. El-Sawy and convert her from Islam to Christianity. Day hired his wife, Catherine Day, to work in his laboratory. Mrs. Day was therefore employed by U-M.

71. During their interactions in Day's laboratory, Mrs. Day engaged in a persistent effort to convert Ms. El-Sawy to Christianity. Mrs. Day made repeated comments dismissive of Ms. El-Sawy's Muslim faith. One of Mrs. Day's techniques was to ask questions that were consistently and obviously designed to degrade Islam and, by implication, Ms. El-Sawy herself. These questions and other dismissive

actions were discriminatory. Day, who supervised both Ms. El-Sawy and his wife in the Department of Urology, was aware of these actions, witnessed them, did not intervene to stop them, and by his silence and, on occasion, nodding approvingly, approved and endorsed them.

*Dr. Day's Harassment Campaign and U-M's Failure to Take EEPI's and Layla El-Sawy's Complaints Seriously*

72. On August 25, 2017, an article was published in *Southernmost Flyer*, a publication produced at the Naval Air Station Key West, Florida, by author Jolene Scholl. Upon information and belief, information therein was provided by Day, who is quoted extensively in the article and has been interviewed by Ms. Scholl. EEPI believed that in these quotes, Day had provided Ms. Scholl with confidential information in violation of the operative contracts.

73. This article was published just one day after Dr. Abdulla Molokhia had emailed Day what would be required for EEPI to accept Day's budget requests.

74. On August 30, 2017, Dr. Abdulla Molokhia, the Vice President of Research and Quality Affairs for Pharco, EEPI's parent company, emailed Day to inform him that, "as of today, we have stopped all direct communication with you as you have done a great damage to our company through breaching our contracts & violating our disclosure agreement and harming the production of the product." Day's violations were therefore not limited to the disclosure and encompassed multiple breaches by Day and U-M, discussed herein. Ms. El-Sawy, Dr. Sherine

Helmy, and several individuals associated with U-M (including the Regents of the University) were copied on Dr. Molokhia's email.

75. Dr. Molokhia's email sparked days of abusive behavior by Day, nearly all of which was directed at Ms. El-Sawy, and that escalated to stalking. On information and belief, Day's abusive actions, like his previous abuse, were motivated by his animus towards Ms. El-Sawy as an Arab, an Egyptian, a Muslim, and a woman. Because of these characteristics, Day perceived Ms. El-Sawy as an attractive target to divert attention from himself for the failures to comply with the parties' agreements and the fundamental flaws in the purported final report.

76. Shortly after Dr. Molokhia sent his email, Day emailed Ms. El-Sawy separately, stating, "Thanks Layla!" It became clear later that this was intended as a sarcastic shot at Ms. El-Sawy, who Day believed had sent a copy of the email to EEPI in an act of disloyalty.

77. Day then responded to Dr. Molokhia's email, copying the same group, and denied that he had breached the contract. He also patronized Dr. Molokhia, Ms. El-Sawy, and the other Egyptians at EEPI, stating in apparent reference to their nationalities, "I think **you people** need to calm down and understand that I did not violate the contract. ... If you void the collaboration at this point **due to your hysterical overreaction to this article** ... then you are at fault. I am very shocked and disappointed by **you people!**" (emphasis added).

78. Day then sent his third email of the day, this time to only Dr. Molokhia, Ms. El-Sawy, and Dr. Sherine Helmy, again asserting he had done nothing wrong. He began openly threatening EEPI, and Ms. El-Sawy, by claiming that if EEPI “want[ed] to pursue this route then go ahead, but I will void any position EEPI has on the patent and challenge any intellectual property you claim to have. If you pursue this breach of contract nonsense you also jeopardize recognition on the scientific article that I will write.”

79. Day sent his fourth and fifth emails of the day minutes later to the same group. Day repeated the same arguments and threatened EEPI again, stating: “You need to call me and explain your position on this immediately or I will proceed as I see necessary and it will not be good for EEPI.” He also specifically threatened to harm Ms. El-Sawy’s professional career: “Layla if you want to be a collaborator of mine and co-author on the paper you should leave EEPI immediately and come back to Michigan.” (Ms. El-Sawy was in Egypt at this time.)

80. Day sent his sixth email of the day, this time to Dr. Molokhia, Ms. El-Sawy, Dr. Sherine Helmy, and Mohamed Desouky, CFO of EEPI. Day asserted, generally, that he was the “principle [sic] investigator” and the “director of research,” and that this meant “I will act in the best interest of the project and do as I think is necessary.” Day then threatened EEPI again, this time with a lawsuit, as well as with an alleged intention to ignore EEPI’s rights under the project and to

only permit U-M to have a claim on any intellectual property. Day asserted in his email that he would pursue these actions “very aggressively and **with the backing of the University of Michigan.**” (emphasis added).

81. Day sent his seventh email of the day, this time to Dr. Molokhia, Ms. El-Sawy, and Dr. Sherine Helmy and in response to Dr. Molokhia’s original morning email. He stated that he was not in breach of contract according to “3 University lawyers,” and stated that “Unless I hear from EEPI by tomorrow, I will instruct UM lawyers to invalidate the patent, which they say is very easily done, based on EEPI’s contract breaches.”

82. Day then returned to form and focused his alarming rage on Ms. El-Sawy. Over just the following days, Day sent *forty-eight* straight missives to Ms. El-Sawy, including emails, text messages, and phone calls. In just the next two days, Day would call, text, or email Ms. El-Sawy forty-one times, including thirty such instances over just a seven-hour period on that same day, August 30, 2017, threatening all manner of adverse actions against her:<sup>2</sup>

**3:22 PM:** Day emails Ms. El-Sawy (his eighth email of the day). In this email, Day specifically threatened that to report Ms. El-Sawy to local Egyptian authorities: “**Layla this is the ministry of health in Egypt directed by Dr. Ahmed Emad El Din Rady. I think he would like, to hear about this story.** Did you read article 15.2 of contract and how it states that if info is already

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<sup>2</sup> All misspellings, grammatical errors, and apparent alterations are in the original, except that where profane terms were used by Day, Plaintiffs have substituted asterisks. Bolded emphasis is supplied.

public I can talk about whatever I want. I AM NOT IN BREACH OF CONTRACT! YOU ARE AND UM LAWYERS ARE GOING TO INVALIDATE EVERYTHING AND I WILL WRITE THE PAPER BASE ON ALLOF [sic.] OTR [sic.] DATA AND I WILL NOT EVEN ACONWLEDGE [sic.] EEPI. Abdulla and sherine [sic] are cheats and liars!”

**4:38 PM:** Day calls Ms. El-Sawy

**4:39 PM:** Day calls Ms. El-Sawy a second time

**4:59 PM:** Day calls Ms. El-Sawy a third time

**5:46 PM:** Day calls Ms. El-Sawy a fourth time. Ms. El-Sawy declines the call and responds via text message, stating: “I’m at the movie theater”

**5:47 PM:** Day responds to Ms. El-Sawy’s text: “U have to call me ASAP. Big problems!!!!”

**5:46 PM:** Day calls Ms. El-Sawy a fifth time

**5:50 PM:** Day texts Ms. El-Sawy: “Layla!!!!!!”

**5:52 PM:** Day texts Ms. El-Sawy: “Everything is off the table”

**6:10 PM:** Day calls Ms. El-Sawy a sixth time

**6:26 PM:** Day texts Ms. El-Sawy: “I will also invalidate the whole project with your ministry of health in Egypt!”

**6:27 PM:** Day texts Ms. El-Sawy: “**Abdulla and sherine have no idea the damage I can do to EEPI! If I want.**”

**6:28 PM:** Day texts Ms. El-Sawy: “Did I know that sherine had published under his name on the patent applications well before I said anything? Why was that not breach of contract?”

**6:30 PM:** Day calls Ms. El-Sawy a seventh time

**6:32 PM:** Day calls Ms. El-Sawy an eighth time

**6:39 PM:** Day calls Ms. El-Sawy a ninth time



**7:57 PM:** Day calls Ms. El-Sawy a tenth time

**7:59 PM:** Day texts Ms. El-Sawy: **“Layla you had better f .... ng call me or you and I are done as friends !!!!!!”** (ellipsis in original)

**8:53 PM:** Day texts Ms. El-Sawy: **“Layla you did this! You showed them the article and trashed my reputation. I am sooo mad at you! You have stabbed me in the back!”**

**8:36 PM:** Day calls Ms. El-Sawy an eleventh time

**8:44 PM:** Day calls Ms. El-Sawy a twelfth time

**8:49 PM:** Day texts Ms. El-Sawy: **“You can no longer access the data on the server. All data is ours for paper and New patents”**

**8:50 PM:** Day texts Ms. El-Sawy: **“Don’t you ever call me again.”**

**9:03 PM:** **Day calls Ms. El-Sawy a thirteenth time**

**9:04 PM:** Day calls Ms. El-Sawy a fourteenth time. Ms. El-Sawy declines the call.

**9:53 PM:** Day texts Ms. El-Sawy: **“Layla I will make sure that the oncology world both academia and industry know how EEPI DOES BUSINESS!”**

**9:55 PM:** Day texts Ms. El-Sawy: **“You have really f\*\*\*ed up!!!”**

**9:59 PM:** Day texts Ms. El-Sawy: **“You had better answer your phone!! If i have to i will fly over there and address this personally with you guys! And it won't be pretty!”**

**10:46 PM:**Day texts Ms. El-Sawy: **“Unless U call me u will never work in science in US AGAIN!”**

**10:46 PM:**Day texts Ms. El-Sawy: **“You had better fix this!”**

83. Except for a single text message (“I’m at the movie theater”) neither Ms. El-Sawy nor any of the other recipients responded to any of Day’s texts, calls, or emails on August 30, 2017.

84. Altogether, on August 31, 2017 between 9:58 AM and 10:46 PM, Day made fourteen calls to Ms. El-Sawy, two of which were made after Day told her, “Don’t you ever call me again.” He also sent fifteen text messages and eight emails to Ms. El-Sawy, including one demand that she call him made after his previous demand to never call him again. That accounts to about one call, text, or email *every twenty minutes*, the vast majority of them threatening Ms. El-Sawy. This does not account for all the forty-eight abusive and deranged missives sent by Day throughout this period of time, detailed previously.

85. In those forty-eight messages, Day threatened to cut Ms. El-Sawy and EEPI out of patents, to contact the Egyptian Minister of Health, apparently to attempt to ruin Ms. El-Sawy’s career and make sure she “will never work in science in US [again]!”, and to “fly over there [to Egypt] and address this personally with you guys! And it won't be pretty!” He also repeated the profane language that Ms. El-Sawy had specifically and repeatedly told Day was offensive to her and harmed her as an Arab, Egyptian, Muslim woman.

86. These actions were part of a pattern with Day’s earlier, repeated verbal comments to Ms. El-Sawy that, *as a white, male, American and a Western man*, he could act with impunity, and no matter what he did to her, he would be believed over her.

87. The next day, August 31, Day resumed his harassment campaign by emailing Marie Eddy, the Research Process Senior Manager in the U-M Department of Urology, and copying Ms. El-Sawy, stating, “I need Layla El-sawy’s [sic.] employment history. Start date and effort.” This email was plainly intended as a threat to Ms. El-Sawy’s employment at U-M.

88. Day sent a second email that day to the day.research.lab@umich.edu listserv, with the subject line “LAYLA,” ordering that all communication with Layla and EEPI be cut off “starting immediately” and that Layla and EEPI be cut off from any access to the lab’s data. Ms. El-Sawy received this email as she was still at that time a recipient of emails sent on the day.research.lab@umich.edu listserv.

89. Also on August 31, Day sent another email to Ms. El-Sawy alone, stating that he had “been talking to a pharmaceutical patent attorney” who told Day “the our [sic] US application ... will be denied based on this paper.”

90. Day sent his fourth email of the day, to Ms. El-Sawy and Dr. Molokhia, stating only, “Just in case you are rethinking your actions,” and attaching an August 28, 2017 letter from Dr. David Bloom, Chair of the U-M Department of Urology, to the EEPI Board of Directors. In that August 28 letter, Dr. Bloom stated that U-M was “committed to supporting Dr. Day in his continuing research collaboration with EEPI.” As of the date of that letter, Dr. Bloom had never met Ms. El-Sawy.

91. On August 31, Day texted Ms. El-Sawy, stating “Layla call me please.” When Ms. El-Sawy did not call him, Day returned to his abusive position, texting: “OK the best thing for You to do is send your letter of resignation immediately.”

92. Day resumed his abusive behavior towards Ms. El-Sawy the next day, September 1, starting in a text message that was clearly manipulative, by alternating between cold and warm and from threats to offers of protection. In so doing, Day sought to shelter his deeds behind, and wield the power of, U-M. Obviously, as his rage dissipated, Day took the full measure of the damage he had caused and attempted to backtrack and protect himself. In full, it stated as follows:

Layla you need to know what is going to happen. Abdulla and sherine will be contacted by the office of general counsel (OGC). They will copy leadership at Pharco as well. Due to abdulla copying the regents of the university of Michigan on his email the most powerful people at the university now know about EEPI, sherine, abdulla and you. They are furious. It is very clear that I did not breach contract. Look at article 15 and 15.2! They have had lawyers look at this And they totally support my position and now believe that EEPI is trying to justify not paying outstanding bills. You should look at contract carefully. **The reputation of EEPI and certain people are going to be ruined at UM and in the scientific Community. If EEPI does not pay immediately they will claim all intellectual property and seize all claims and rights to the project.** This is in the contract! They will move to

invalidate patents and **will prosecute EEPI in international court.** They want to know why you, a UM employee, have done this to your employer!

**You know I am mad but I am calming down. Now I am very worried about your scientific reputation.** If u call and talk to

me I will protect you as much as I can. **They suggested that I block you from getting access to our data bases. That is standard procedure.** You have to call me. I don't think u understand how bad this is going to get. **Sherine and abdulla have USED you in this! I have taken care of you and your scientific career and reputation has flourished under me, but it is in jeopardy.**

**If we talk I will do what I can to protect you.** But you have to call me today!!

93. The next day, September 2, Ms. El-Sawy received an automated text message sent by Ms. El-Sawy's cellular telephone service provider informing her that Day had called her three times: "This number tried to call 3 times the last time on 02/09 [September 2] at 1:41." Ms. El-Sawy had earlier blocked phone calls from Day's number. Those calls were each made on September 1 and 2, 2017.

94. Day sent another email to Ms. El-Sawy about the paper on September 6, deflecting all blame for the recent events onto her alone. Day sent yet another email minutes later, again threatening Ms. El-Sawy with legal action.

95. Also on September 6, 2017, Day texted Ms. El-Sawy: "Layla you need to call me to know what is going on."

96. This was additional evidence of Day's plan to target Ms. El-Sawy as the scapegoat for his own actions, including his breaches of the parties' agreements. It was clear to Ms. El-Sawy and EEPI that Day was targeting her with his escalating threats both because she was an Arab, Egyptian, Muslim woman who was uniquely

vulnerable to his abusive behavior, and because he believed that this would make her uniquely vulnerable to his abusive behavior.

97. Day's discriminatory and unconstitutional behavior has caused substantial physical, mental, psychic, and professional damage to Ms. El-Sawy, who emerged from the ordeal with a cardiac condition aggravated by Day's shocking behavior.

98. Day was aware of Ms. El-Sawy's cardiac condition, and Day and his employees had in fact witnessed her experience several cardiac events. This included cardiac events in the laboratory on January 23, 2015, which was witnessed by Mrs. Day; on March 7, 2015, which was witnessed by Day himself; and on April 3, 2017, which Day may not have personally witnessed but which occurred when Day was in the laboratory and about which he was informed.

99. Day's stalking of late August and early September 2017 was the but-for and proximate cause of a cardiac event experienced by Ms. El-Sawy on September 2, 2017. Ms. El-Sawy was at her home in Alexandria, Egypt and felt immense stress brought on by Day's stalking. She began to suffer severe chest pain. Anticipating another cardiac spasmodic crisis, she called her physician, who visited and treated her at home around 6:00 pm. Ms. El-Sawy was asked by her physician if she was experiencing any stress, and she told him about Day's stalking and mistreatment.

100. Ms. El-Sawy's treating physician has observed that, over time, Ms. El-Sawy's condition has deteriorated, has attributed that deterioration to stress, has deemed that further treatment might be necessary as a consequence of that stress, and has recommended to Ms. El-Sawy that she avoid exposing herself to such stress.

101. On September 14, 2017, Malissa Eversole, the Clinical Department Administrator for the U-M Department of Urology, emailed Ms. El-Sawy to schedule a disciplinary review phone conference call.

102. Ms. El-Sawy's counsel emailed Ms. Eversole on September 15, 2017 to inform her he was acting on Ms. El-Sawy's behalf and request that any further communication be made to that counsel.

103. Ms. Eversole missed the September 15, 2017 email from Ms. El-Sawy's counsel. On September 20, 2017, Ms. Eversole scheduled a conference call without input from Ms. El-Sawy, evidently believing Ms. El-Sawy had ignored Ms. Eversole's September 14 email. Ms. El-Sawy's counsel followed up with Ms. Eversole the following day.

104. On September 26, 2017, Day informed Ms. El-Sawy's counsel that he and U-M would be jointly represented by an attorney from the U-M Office of the General Counsel. That attorney confirmed in writing that he was representing U-M on September 29, 2017, saying nothing about Day.

105. On September 27, 2017, Ms. Eversole informed Ms. El-Sawy's counsel that U-M had unilaterally decided to suspend Ms. El-Sawy's pay for failure to perform her work duties. Ms. Eversole required a reply by October 3, 2017, or else U-M would initiate disciplinary procedures against Ms. El-Sawy.

106. This suspension of pay for supposed non-performance of work duties was done despite Day's earlier actions to prevent Ms. El-Sawy from accessing any data or otherwise performing any of her job responsibilities. Ms. El-Sawy's counsel informed Ms. Eversole of this on September 28, 2017.

107. On October 3, 2017, EEPI and Ms. El-Sawy, through their attorney, filed a complaint against Day according to U-M's internal procedures (the "First Misconduct Complaint" or "1MC"). In the First Misconduct Complaint, Plaintiffs described, *inter alia*, Day's mistreatment of Ms. El-Sawy, countered false accusations Day had leveled against EEPI, and described the contractual breaches committed by Day.

108. The First Misconduct Complaint asked for "UM to formally inquire into the matter, to take the most radical measures for protecting their interests and to pronounce against Dr. Day the harshest disciplinary measures permitted by UM's ethics."

109. The First Misconduct Complaint also described an effort by Day to interfere with Ms. El-Sawy's ability to be fairly treated by U-M. Among other things,



Day had undertaken a campaign to ensure that U-M would act, or appear to act, without neutrality and with a bias in favor of Day. This includes Day's aforementioned assertions to Ms. El-Sawy that he had approached and had extensive conversations with the U-M Office of the General Counsel and other unnamed "University lawyers." These included assertions that Day made to Ms. El-Sawy that Day would "instruct UM lawyers to invalidate the patent, which they say is very easily done," and that "I AM NOT IN BREACH OF CONTRACT YOU ARE AND UM LAWYERS ARE GOING TO INVALIDATE EVERYTHING." (emphasis in original text message). These actions were intended to influence U-M against Ms. El-Sawy and EEPI and convince them that U-M could not undertake a neutral investigation of Day's misconduct.

110. On November 1, 2017, Ms. Eversole emailed Ms. El-Sawy's counsel and informed him that a disciplinary review conference had been scheduled for the next day, November 2. Ms. Eversole did not state who the subject of the conference was to be or provide any other details. Ms. El-Sawy's counsel objected to the conference, and Ms. Eversole agreed to postpone it.

111. Upon Ms. El-Sawy's request for clarifications, an employee from the Office of the General Counsel informed Ms. El-Sawy's counsel on November 3, 2017 that the disciplinary review conference proceedings would be directed *against* Ms. El-Sawy for her supposed non-performance of her job duties, emphasizing

multiple times that termination was a possible outcome. The Office of the General Counsel further informed Ms. El-Sawy's counsel that Day would be participating in those proceedings.

112. Then, on November 7, 2017, the same employee emailed Ms. El-Sawy's counsel, saying that the disciplinary review conference had "been placed on hold while the department and HR further consider[ed] this matter."

113. The disciplinary review conference proceedings constituted retaliation against Ms. El-Sawy, initiated by Day and supported by U-M.

114. On November 20, 2017, the Office of the General Counsel forwarded a letter from Dr. Bloom to Ms. El-Sawy's counsel. Dr. Bloom's letter expressed sympathy to Ms. El-Sawy for having endured Day's misconduct and "requesting an opportunity to meet with [her] to discuss the particulars of [her] complaint," at which she could be assisted by counsel. She was told this would not be a disciplinary investigation.

115. U-M and Ms. El-Sawy negotiated the terms of this meeting, which was conducted via telephone conference, through counsel.

116. On February 7, 2018, the video conference was held. The attendees included Ms. El-Sawy, Ossama Elkaffash, Director at Pharco, John Liebeskind, attorney for Ms. El-Sawy, Dr. David Bloom, Chair of the U-M Department of Urology, Dr. John Wei, Associate Chair of the U-M Department of Urology, and

Malissa Eversole, Clinical Department Administrator of the U-M Department of Urology.

117. During the conference, Ms. El-Sawy discussed the pattern of abuse and discrimination that she suffered while working under Day and the subsequent discriminatory retaliation for raising complaints with Day and U-M's contractual performance. Her intense trauma is clear during the call, in which she can nearly constantly be heard crying, panting, and struggling to breathe in a nearly hysterical state. Crucially, Ms. El-Sawy made clear that Day's misconduct was directed at her specifically "because I am a Muslim, because I am from Egypt."

118. Most or all of the U-M employees made it clear that they agreed Day's actions had been inappropriate and unacceptable. Dr. Bloom, for example, stated that "my sympathy is closer to you [Layla El-Sawy]" than to Day and apologized to her on behalf of U-M. Dr. John Wei, Associate Chair of the U-M Department of Urology, told Layla El-Sawy "you are not in trouble," and apologized for any communications that indicated that she was in trouble (presumably referring to Day's repeated threats). Malissa Eversole also apologized on behalf of U-M and reiterated that their sympathy in the situation lay with Ms. El-Sawy, not with Day. Ms. Eversole also stated, discussing Day's actions, that "we do not condone that behavior, that will not be tolerated." Many of these thoughts were expressed *after*

Ms. El-Sawy made clear that Day's actions were the result of his animus towards her religion and national origin.

119. Ms. El-Sawy was asked to speak on several topics during the conference. Among other things, she stated that Day's actions had "emotionally and physically destroyed her." She also revealed that Day's misconduct had caused harm to her own reputation and destroyed her "career wise," and felt that it was especially unfair considering that she had been the person to bring Day to EEPI in the first instance.

120. On March 16, 2017, after the telephone conference, a second, complementary complaint for misconduct was filed according to U-M's internal procedures (the "Second Misconduct Complaint"). This Second Misconduct Complaint detailed, *inter alia*, further abusive and discriminatory actions by Day against Ms. El-Sawy and the aggravation of her cardiac condition that resulted from the same.

121. On April 10, 2018, Day wrote a letter apologizing to Ms. El-Sawy.

122. On July 17, 2018, on EEPI's counsel request, Day wrote a second apology letter, this time apologizing to Dr. Sherine Helmy, the owner of Pharco, and Dr. Molokhia, the director of the research project.

123. On November 6, 2018, a third complaint was filed according to U-M's internal procedures (the "First Noncompliance Complaint" or "1NC"). The First

Noncompliance Complaint detailed U-M's failure to take appropriate action following the filing of the First Misconduct Complaint. In particular, and as the 1NC detailed, despite repeated attempts to contact U-M's compliance hotline and other compliance departments, the misconduct perpetrated by Day and others against Ms. El-Sawy and EEPI had been ignored.

124. When the First Noncompliance Complaint was filed, the First Misconduct Complaint remained unanswered.

125. The 1NC was filed against, among others, members of the Office of the General Counsel, and therefore expressly demanded that the 1NC not be handled by that Office to avoid conflicts of interest and a possible denial of Plaintiffs' due process rights. Plaintiffs therefore requested that the 1NC be handled by the Office of University Audits.

126. The 1NC detailed how Day had tainted the ability of the individuals at U-M charged with analyzing the complaints of Ms. El-Sawy and EEPI to neutrally discharge those duties. It also detailed how U-M had ignored those concerns.

127. Also on November 6, 2018, a fourth complaint was filed according to U-M's internal procedures (the "Third Misconduct Complaint"). The Third Misconduct Complaint detailed, *inter alia*, Day's misconduct in the pursuit of research during the project.

128. Among other things, the Third Misconduct Complaint demonstrated that the Final Report which was required to be filed at the end of the Second Research Agreement contained a conclusion which did not follow from the data and followed a method which was scientifically unsound. As a result, the Final Report was scientifically and economically worthless. Because EEPI could not use the final report's conclusions or data, all of the money EEPI had spent on the project had been a waste.

129. Importantly, the flaws in the Final Report meant that, irrespective of the efficacy of the use of Ambrosia in treating cancer, EEPI would be unable to use the money and time spent on this research to further its goal of marketing and selling a drug it developed.

130. The 3MC rested on two reports prepared by experts on the relevant subjects. Both of those expert reports concluded that the final report, as submitted, contained multiple flaws.

131. On November 21, 2018, Dr. Bloom informed counsel for Ms. El-Sawy and EEPI that "a scientific audit has started and I'm told it will take some considerable time." The same counsel was informed one month later, on December 21, that the investigation was ongoing.

132. Also on November 21, 2018, Dr. Bloom informed the same counsel that, per prior requests, a “financial audits,” which had been requested into Day’s use of funds for inappropriate personal items, “are already in play.”

133. The financial audits were never provided to EEPI.

134. On May 28, 2019, Dr. Bloom wrote in a letter to Ms. El-Sawy, among other things, the following:

... we had to resolve some accusation regarding details of that work to our satisfaction. After a number of months some colleagues here in the university, whom I trust deeply, have done so - showing that while some minor errors in a graph, for example, were present, the integrity of the work it itself is not in doubt. Over the several decades of my experience with the Day lab, research misconduct have [sic] never been an issue.

135. Dr. Bloom’s May 28, 2019 letter did not detail any support for his conclusion. It ignored multiple flaws altogether, except for a single vague reference to a graph.

136. The May 28, 2019 letter reiterated that the Final Report was, nevertheless, *not* satisfactory of the obligations under the contract, as Dr. Bloom wrote: “We all agree EEPI is due a revised and better final report. Dr. Day has ensured us that he will produce this work.” That second, revised, “better” report was never provided. The “financial audits” that Plaintiffs were told were being conducted were not mentioned.

137. On June 11, 2020, a fifth and final complementary complaint was filed with U-M using its internal procedures (the “Second Noncompliance Complaint” or “2NC”). The 2NC detailed the further failures of U-M to investigate the misconduct alleged by Ms. El-Sawy against Day, and his nonperformance of the Research Agreements.

138. Despite the demand in the Second Noncompliance Complaint that the same not be handled by members of the Office of the General Counsel against whom it was directed, that was exactly what happened.

139. The 2NC detailed how, following the filing of the 1NC, Plaintiffs were unable to get anyone at U-M to respond to any of the misconduct demonstrated in *any* of the Misconduct Complaints.

140. Ms. El-Sawy reasonably expected to write and publish several academic papers regarding *A. maritima*. Through her time there, due to Day’s malevolence, she was unable to publish a single paper.

141. In his two apology letters, Day committed to collaborate with Ms. El-Sawy on the publication of two papers. Between April 2018 and January 2019, Ms. El-Sawy put aside her concerns about working with Day and collaborated on the papers in an attempt to salvage something from the enormous investment of time and resources by Ms. El-Sawy and EEPI.



142. Nevertheless, despite Ms. El-Sawy's best efforts and intent to publish these papers, the papers were never completed.

143. This large gap on her publishing résumé has caused, is still causing, and will continue to cause substantial and irreparable damage to Ms. El-Sawy's professional career and reputation as an academic.

**COUNT I**  
**VIOLATION OF 42 USC § 1983**  
**(EQUAL PROTECTION CLAUSE—DISCRIMINATION ON THE BASIS**  
**OF SEX, RACE, RELIGION, AND NATIONAL ORIGIN)**  
**(Against U-M and Day in His Official Capacity)**

144. Plaintiffs reallege and incorporate all proceeding paragraphs as if fully restated herein.

145. Section 1 of the Fourteenth Amendment provides, "No state shall ... deny to any person within its jurisdiction the equal protection of the laws."

146. Pursuant to 42 USC § 1983, in relevant part, "Every person who, under color of any statute, ordinance, regulation, custom, or usage, of any State or Territory or the District of Columbia, subjects, or causes to be subjected, any citizen of the United States or other person within the jurisdiction thereof to the deprivation of any rights, privileges, or immunities secured by the Constitution and laws, shall be liable to the party injured in an action at law, suit in equity, or other proper proceeding for redress...."

147. The University of Michigan is a public university and an arm of the State of Michigan subject to the United States Constitution.

148. Defendants Day and U-M and other U-M employees acted under color of state law when taking the actions described in this Count.

149. Defendant Day, who runs Day Labs in the Department of Urology at U-M, is an official with final policymaking authority whose decisions may be fairly said to represent official policy. According to Defendant Day himself, he is an official with final policymaking authority whose decisions must be understood by his associates to represent official policy.

150. The only purpose of Ms. El-Sawy's employment with U-M was to further her work on *A. maritima* seeking medicinal applications of that compound. There was no reason for her to remain at U-M if she could not continue that work.

151. The behavior of Day and Mrs. Day, under the color of state law, resulted in the constructive discharge of Ms. El-Sawy.

152. That behavior included, but was not limited to:

- a. First, Defendant Day, in his official capacity as a professor employed by the University of Michigan Department of Urology, demeaned and verbally attacked Ms. El-Sawy, by virtue of her status as a woman, as an Arab, as an Egyptian, as a Muslim, and as a naturalized citizen, and continuously engaged in profane language aimed at Ms. El-Sawy.

Defendant Day aimed this behavior at Ms. El-Sawy because Day understood that Ms. El-Sawy was particularly susceptible to being harmed by such profane behavior.

- b. Second, Defendant Day, in his official capacity as a professor employed by the University of Michigan Department of Urology as well as in his individual capacity, asserted his dominance over Ms. El-Sawy by virtue of his status as a “Western,” white, American male.
- c. Third, Mrs. Day, in her official capacity as an employee of the University of Michigan Department of Urology, attempted to use her position as an employee of the state to demean Ms. El-Sawy’s religion and attempt to convert her from one religion to another. Defendant Day supported, encouraged, and did nothing to interfere with this extreme and outrageous behavior.
- d. Finally, Defendant Day, in his official capacity as a professor employed by the University of Michigan as well as in his individual capacity, harassed and stalked Ms. El-Sawy after EEPI informed him of its intent to terminate its agreements with U-M and Day, as described in detail in the General Allegations. This behavior was motivated by Day’s animus for Ms. El-Sawy as a woman, as a Muslim, as an Arab and as an Egyptian.

153. Defendants deprived Ms. El-Sawy's of her right pursuant to Section 1 of the Fourteenth Amendment to the equal protection of the law when she was constructively discharged on account of her sex, race, religion, national origin, and alienage.

154. Defendants constructively discharged Ms. El-Sawy when they held a hearing, promised through Dr. Bloom to help Ms. El-Sawy retain her position if she desired to and preserve her career, and then failed to satisfy those promises. U-M, and in particular, the Office of General Counsel, failed to take steps to protect Ms. El-Sawy. This included a failure to follow through on promised audits of Day's behavior and a refusal to provide Ms. El-Sawy with access to the project's data, according to Day's instructions, so she could continue her work.

155. Defendants intentionally and purposefully discriminated against Ms. El-Sawy on account of her sex, race, religion, national origin, and alienage. Day made this clear, *inter alia*, by way of his comments that as a Western, white, American man (as opposed to Ms. El-Sawy, an Arab, Egyptian, Muslim woman who was a naturalized citizen from the "East"), Day could act with impunity towards Ms. El-Sawy.

156. Defendants acted with a reckless or callous disregard of, or indifference to, the rights and safety of Ms. El-Sawy.

157. This discriminatory and unconstitutional behavior has caused substantial physical, mental, psychic, monetary, and professional damage to Defendants, including to Ms. El-Sawy, who emerged from the ordeal with a cardiac condition aggravated by these unlawful actions.

**COUNT II**  
**VIOLATION OF 42 USC § 1983**  
**(EQUAL PROTECTION CLAUSE—HOSTILE WORK ENVIRONMENT)**  
**(Against U-M and Day in His Official Capacity)**

158. Plaintiffs reallege and incorporate all proceeding paragraphs as if fully restated herein.

159. Section 1 of the Fourteenth Amendment provides, “No state shall ... deny to any person within its jurisdiction the equal protection of the laws.”

160. Pursuant to 42 USC § 1983, in relevant part, “Every person who, under color of any statute, ordinance, regulation, custom, or usage, of any State or Territory or the District of Columbia, subjects, or causes to be subjected, any citizen of the United States or other person within the jurisdiction thereof to the deprivation of any rights, privileges, or immunities secured by the Constitution and laws, shall be liable to the party injured in an action at law, suit in equity, or other proper proceeding for redress....”

161. The University of Michigan is a public university and an arm of the State of Michigan subject to the United States Constitution.

162. Defendants Day and U-M and other U-M employees acted under color of state law when taking the actions described in this Count.

163. Defendant Day, who runs Day Labs in the Department of Urology at U-M, is an official with final policymaking authority whose decision may be fairly said to represent official policy. According to Defendant Day himself, Day is an official with final policymaking authority whose decisions must be understood by his associates to represent official policy.

164. The only purpose of Ms. El-Sawy's employment with U-M was to further her work on *A. maritima* seeking medicinal applications of that compound. There was no reason for her to remain at U-M if she could not continue that work.

165. The behavior of Day and Mrs. Day, under the color of state law, resulted in a hostile work environment which was permeated with discriminatory intimidation, abuse, ridicule, and insults, that was sufficiently severe or pervasive to alter the conditions of the Ms. El-Sawy's employment.

166. That behavior included, but was not limited to:

- a. First, Defendant Day, in his official capacity as a professor employed by the University of Michigan Department of Urology, demeaned and verbally attacked Ms. El-Sawy, by virtue of her status as a woman, as an Arab, as an Egyptian, as a Muslim, and as a naturalized citizen, and continuously engaged in profane language

aimed at Ms. El-Sawy. Defendant Day aimed this behavior at Ms. El-Sawy because Day understood that Ms. El-Sawy was particularly susceptible to being harmed by such profane behavior.

- b. Second, Defendant Day, in his official capacity as a professor employed by the University of Michigan Department of Urology as well as in his individual capacity, asserted his dominance over Ms. El-Sawy by virtue of his status as a “Western,” white, American male.
- c. Third, Mrs. Day, in her official capacity as an employee of the University of Michigan Department of Urology, attempted to use her position as an employee of the state to demean Ms. El-Sawy’s religion and attempt to convert her from one religion to another. Defendant Day supported, encouraged, and did nothing to interfere with this extreme and outrageous behavior.
- d. Finally, Defendant Day, in his official capacity as a professor employed by the University of Michigan as well as in his individual capacity, harassed and stalked Ms. El-Sawy after EEPI informed him of its intent to terminate its agreements with U-M and Day, as described in detail in the General Allegations. This behavior was

motivated by Day's animus for Ms. El-Sawy as a woman, as an Arab, as an Egyptian, and as a Muslim.

167. The work environment to which Ms. El-Sawy was subjected was objectively hostile and abusive.

168. Defendants deprived Ms. El-Sawy's of her right pursuant to Section 1 of the Fourteenth Amendment to not be denied the equal protection of the laws by altering the terms of her employment by means of this hostile work environment.

169. Defendants' behavior was severe, physically threatening, frequent, pervasive, and humiliating.

170. Defendants acted with a reckless or callous disregard of, or indifference to, the rights and safety of Ms. El-Sawy.

171. This discriminatory and unconstitutional behavior has caused substantial physical, mental, psychic, and professional damage to Ms. El-Sawy, who emerged from the ordeal with a cardiac condition aggravated by these unlawful actions.

**COUNT III**  
**VIOLATION OF 42 USC § 1983**  
**(FIRST AMENDMENT ESTABLISHMENT CLAUSE AND**  
**FOURTEENTH AMENDMENT DUE PROCESS CLAUSE)**  
**(Against U-M and Day in His Official Capacity)**

172. Plaintiffs reallege and incorporate all proceeding paragraphs as if fully restated herein.



173. The First Amendment to the US Constitution provides that “Congress shall make no law respecting an establishment of religion.” The First Amendment to the US Constitution is incorporated against state governments through the Due Process Clause of the Fourteenth Amendment. *See Everson v. Board of Education*, 330 US 1 (1947).

174. The University of Michigan is a public university and an arm of the State of Michigan subject to the United States Constitution.

175. Defendants Day and U-M, Mrs. Day, and other U-M employees acted under color of state law when taking the actions described in this Count.

176. Defendant Day, who runs Day Labs in the Department of Urology at U-M, is an official with final policymaking authority whose decision may be fairly said to represent official policy. According to Defendant Day himself, Day is an official with final policymaking authority whose decisions must be understood by his associates to represent official policy.

177. Mrs. Day’s actions, by which she intended to promote her religion above that of Ms. El-Sawy’s and to convert Ms. El-Sawy from Islam to Christianity, which were viewed by, approved by, and encouraged by her supervisor, Day, constituted government speech in endorsement of religion in contravention of the Establishment Clause.

178. U-M's and Mrs. Day's actions deprived Ms. El-Sawy of her constitutional right under the Establishment Clause of the First Amendment to the United States Constitution, as incorporated against the states through the Due Process Clause of the First Amendment.

179. Defendants and Mrs. Day acted with a reckless or callous disregard of, or indifference to, the rights and safety of Ms. El-Sawy.

180. This discriminatory and unconstitutional behavior has caused substantial physical, mental, psychic, monetary, and professional damage to Defendants, including to Ms. El-Sawy, who emerged from the ordeal with a cardiac condition aggravated by these unlawful actions.

**COUNT IV**  
**INTENTIONAL INFLICTION OF EMOTIONAL DISTRESS**  
**(By Ms. El-Sawy Against U-M and Day in His Official  
and Individual Capacities)**

181. Plaintiffs reallege and incorporate all proceeding paragraphs as if fully restated herein.

182. Day and the University of Michigan engaged in a pattern of extreme and outrageous behavior which, whether taken individually or as a whole, constitutes tortious conduct.

183. First, Day, in his official capacity as a professor employed by the University of Michigan Department of Urology, engaged in extreme and outrageous behavior when he demeaned and verbally attacked Ms. El-Sawy, by virtue of her

status as a woman, as an Arab, as an Egyptian, and as a Muslim, and continuously engaged in profane language aimed at Ms. El-Sawy. Day aimed this behavior at Ms. El-Sawy because Day understood that Ms. El-Sawy was particularly susceptible to being harmed by such profane behavior.

184. Second, Day, in his official capacity as a professor employed by the University of Michigan Department of Urology as well as in his individual capacity, engaged in extreme and outrageous behavior when he asserted his dominance over Ms. El-Sawy by virtue of his status as a “Western,” white, American male.

185. Third, Mrs. Day, in her official capacity as an employee of the University of Michigan Department of Urology, engaged in extreme and outrageous behavior when she attempted to use her position as an employee of the state to demean Ms. El-Sawy’s religion and attempt to convert her from one religion to another. Day supported, encouraged, and did nothing to interfere with this extreme and outrageous behavior.

186. Finally, Day, in his official capacity as a professor employed by the University of Michigan as well as in his individual capacity, engaged in extreme and outrageous behavior by harassing and stalking Ms. El-Sawy after EEPI informed him of its intent to terminate its agreements with U-M and Day, as described in detail herein.

187. Day’s behavior was intentional or reckless.

188. All of Day's behavior was driven by his animus for Ms. El-Sawy as a woman, as an Arab, as an Egyptian, and as a Muslim.

189. Day's harassment and stalking of Ms. El-Sawy was additionally driven by his mistaken belief that Ms. El-Sawy had been "disloyal" to him and had convinced EEPI to cancel its agreements with U-M and Day and based on his plan to target Ms. El-Sawy as a scapegoat based on her unique vulnerability as an Arab, as a Muslim, and as an Egyptian.

190. Day's behavior as detailed in this Count as well as in the General Allegations caused severe emotional distress to Ms. El-Sawy.

191. Along with such severe emotional distress, Day's behavior also caused substantial physical, mental, and psychic damage to Ms. El-Sawy

192. Day's behavior constituted the proximate and but-for cause of the severe emotional distress alleged herein, including Ms. El-Sawy's aggravated cardiac condition.

193. Day was acting within the scope of his authority as a professor employed by the University of Michigan Department of Urology and supervisor of the Day Laboratory when he engaged in this extreme and outrageous behavior. As such, U-M is vicariously liable for Day's extreme and outrageous behavior.

194. Day's extreme and outrageous behavior has caused substantial physical, mental, psychic, and professional damage to Ms. El-Sawy.

**COUNT V**  
**VIOLATION OF THE ELLIOT-LARSEN CIVIL RIGHTS ACT**  
**(Against U-M and Day in his Official and Individual Capacities)**

195. Plaintiffs reallege and incorporate all proceeding paragraphs as if fully restated herein.

196. The only purpose of Ms. El-Sawy's employment with U-M was to further her work on *A. maritima* seeking medicinal applications of that compound. There was no reason for her to remain at U-M if she could not continue that work.

197. The behavior of Day and Mrs. Day resulted in the constructive discharge of Ms. El-Sawy.

198. That behavior included, but was not limited to:

- a. First, Defendant Day, in his official capacity as a professor employed by the University of Michigan Department of Urology, demeaned and verbally attacked Ms. El-Sawy, by virtue of her status as a woman, as an Arab, as an Egyptian, as a Muslim, and as a naturalized citizen, and continuously engaged in profane language aimed at Ms. El-Sawy. Defendant Day aimed this behavior at Ms. El-Sawy because Day understood that Ms. El-Sawy was particularly susceptible to being harmed by such profane behavior.
- b. Second, Defendant Day, in his official capacity as a professor employed by the University of Michigan Department of Urology as

- well as in his individual capacity, asserted his dominance over Ms. El-Sawy by virtue of his status as a “Western,” white, American male.
- c. Third, Mrs. Day, in her official capacity as an employee of the University of Michigan Department of Urology, attempted to use her position as an employee of the state to demean Ms. El-Sawy’s religion and attempt to convert her from one religion to another. Defendant Day supported, encouraged, and did nothing to interfere with this extreme and outrageous behavior.
- d. Finally, Defendant Day, in his official capacity as a professor employed by the University of Michigan as well as in his individual capacity, harassed and stalked Ms. El-Sawy after EEPI informed him of its intent to terminate its agreements with U-M and Day, as described in detail in the General Allegations. This behavior was motivated by Day’s animus for Ms. El-Sawy as a woman, as an Arab, as an Egyptian, and as a Muslim.

199. Defendants constructively discharged Ms. El-Sawy when they held a hearing, promised through Dr. Bloom to help Ms. El-Sawy retain her position if she desired to and preserve her career, and then failed to satisfy those promises. U-M, and in particular, the Office of General Counsel, failed to take steps to protect Ms.

El-Sawy. This included a failure to follow through on promised audits of Day's behavior and a refusal to provide Ms. El-Sawy with access to the project's data, according to Day's instructions, so she could continue her work.

200. Defendants intentionally and purposefully discriminated against Ms. El-Sawy on account of her sex, race, religion, national origin, and alienage. Day made this clear, *inter alia*, by way of his comments that as a Western, white, American man (as opposed to Ms. El-Sawy, an Arab, Egyptian, Muslim woman who was a naturalized citizen from the "East"), Day could act with impunity towards Ms. El-Sawy.

201. Defendants acted with a reckless or callous disregard of, or indifference to, the rights and safety of Ms. El-Sawy.

202. Unlawful discrimination was at the very least a motivating factor in Defendants' constructive discharge of Ms. El-Sawy.

203. Defendants would not have constructively discharged Ms. El-Sawy if not for their discriminatory motive.

204. Ms. El-Sawy is a woman, Arab, Egyptian, Muslim, and a person of color, and is therefore a member of a protected class.

205. Ms. El-Sawy was subjected to an adverse employment action when she was, *inter alia*, constructively discharged.

206. Ms. El-Sawy was qualified for the position that she held at U-M.

207. Ms. El-Sawy was treated differently than similarly situated men, white individuals, Christian individuals, and native-born American individuals who worked in Day's Laboratory and at U-M.

208. This discriminatory and unconstitutional behavior has caused substantial physical, mental, psychic, monetary, and professional damage to Defendants, including to Ms. El-Sawy, who emerged from the ordeal with a cardiac condition aggravated by these unlawful actions.

**COUNT VI**  
**BREACH OF CONTRACT**  
**(DAY CONSULTING AGREEMENT)**  
**(By EEPI Against Day in His Individual Capacity)**

209. Plaintiffs reallege and incorporate all proceeding paragraphs as if fully restated herein.

210. EEPI entered into a valid and binding contract with Day in his individual capacity, dated July 9, 2013 (the "Day Consulting Agreement").

211. U-M was not a party to the Day Consulting Agreement. Day entered into the Day Consulting Agreement with EEPI and Pharco as an independent contractor entirely separate from his relationship with U-M.

212. Day was not acting under color of state law when entering into, negotiating, performing, breaching, or otherwise acting with relation to the Day Consulting Agreement.



213. Day was not acting in his capacity as a professor or otherwise as an employee of U-M when entering into, negotiating, performing, breaching, or otherwise acting with relation to the Day Consulting Agreement.

214. Day received compensation under the Day Consulting Agreement directly from EEPI.

215. The Day Consulting Agreement was extended three times, once in 2014, once in 2015, and once in 2016. The final extension of the Day Consulting Agreement concluded on August 9, 2017.

216. The Day Consulting Agreement required Day to undertake four actions, as follows:

1. Dr. Day will continue to advise Dr. Layla El-Sawy (head of the Molecular Medicine Laboratory at EEPI) in establishing a bladder cancer research program at EEPI. This will include training Dr. El-Sawy in the development of cell based preclinical models of prostate and bladder cancer and in the establishment of the bladder cancer specimen procurement program at EEPI.
2. Dr. Day will advise EEPI on the progress of preclinical testing of FXY204 and the development of metalloproteinase inhibitors of ADAM15.
3. Dr. Day will consult on the establishment of the Helmy Institute of Research and the scientific focus of this institute.
4. Dr. Day will advise EEPI on the scientific merit of new anticancer agents discovered by EEPI. This will only include review of data as any further analysis by Dr. Days lab at the University of Michigan will need to be negotiated separately from the consulting agreement.

217. The Day Consulting Agreement required Day to “generate 4 quarterly reports for EEPI detailing developments on all 4 topics,” which topics were those actions listed in the preceding Paragraph of this Complaint.

218. Day breached the Day Consulting Agreement by, *inter alia*, failing to provide the quarterly reports required by that Agreement.

219. Day’s further breached his duty to “advise EEPI on the progress of preclinical testing of FXY204 and the development of metalloproteinase inhibitors of ADAM15” (“Obligation No. 2”).

220. In order to satisfy Obligation No. 2, Day was required, at a minimum, to analyze the quality of the research methods used and the reliability of the results.

221. Day breached Obligation No. 2 by failing to advise EEPI of scientific fraud and incompetence occurring in the study.

222. Day further breached Obligation No. 2 by taking action to conceal from EEPI the same scientific fraud and incompetence occurring in the study.

223. Day further breached Obligation No. 2 by failing to advise EEPI that the final report provided out of the study was based on flawed methodology and data, which rendered that report useless.

224. Day further breached Obligation No. 2 by failing to deploy his professional expertise when advising EEPI.

225. As a result of Day's breaches of the Day Consulting Agreement, EEPI suffered damage as it did not receive the Reports it had contracted for. As such, the final report could not be used for its intended purpose, i.e., marketing and selling a drug developed through the project.

226. As a result of Day's breaches of the Day Consulting Agreement, EEPI was damaged by Day's failure to provide EEPI with accurate advice regarding the flawed methodology and data used in the final report, which was rendered useless. As such, the final report could not be used for its intended purpose, i.e., marketing and selling a drug developed through the project.

**COUNT VII**  
**BREACH OF CONTRACT**  
**(FIRST RESEARCH AGREEMENT, FIRST AMENDMENT, AND**  
**SECOND RESEARCH AGREEMENT)**  
**(By EEPI Against U-M)**

227. Plaintiffs reallege and incorporate all proceeding paragraphs as if fully restated herein.

228. Based on the discussions between U-M, Day, and EEPI leading to the execution of the Second Research Agreement, U-M and Day knew and understood that EEPI expected that the study contemplated by the Second Research Agreement (the "Preclinical Phase") would be planned and conducted in a manner calculated to support, if justified by the scientific results, the transition to clinical trials of the FXY anti-cancer agent.

229. To induce EEPI to enter into the Second Research Agreement at the contractual end of the First Research Agreement, U-M and Day represented to EEPI, expressly and/or by clear implication, that a successful result in the Preclinical Phase would enable the Project to proceed to clinical testing.

230. If U-M or Day had advised EEPI that the Preclinical Phase would have to be followed by yet another preclinical study using GLP before proceeding with clinical investigations, EEPI would not have agreed to pay an additional \$1,500,000 for the Preclinical Phase following the investigative phase contemplated the First Research Agreement. Instead, EEPI would have chosen to complete the Investigative Phase and then proceed with a GLP-compliant preclinical study.

231. For the foregoing reasons, it was an implied term of the Second Research Agreement that the Preclinical Phase would be conducted in compliance with GLP.

232. For the foregoing reasons, it is also a usage of trade in the relevant place, vocation, and/or trade that a study constituting a preclinical phase of a project involving a drug which may potentially have medicinal uses will be conducted in compliance with GLP.

233. To satisfy the requirements of GLP, a preclinical study must be conducted in accordance with a written protocol that meets the requirements of 21 CFR 58.120 (each a “Protocol”).

234. EEPI and Day conducted the Preclinical Phase without preparing or following a Protocol.

235. To satisfy the requirements of GLP, a preclinical study must be directed by an individual (the “Study Director”) having the appropriate education, training, and experience to conduct the study in accordance with GLP.

236. The Preclinical Phase was conducted in the absence of a Study Director having the appropriate education, training, and experience to conduct the Preclinical Phase in accordance with GLP.

237. To satisfy the requirements of GLP, a preclinical study must conclude with a Final Report meeting the requirements of 21 CFR 58.185.

238. U-M and Day failed to deliver a final report for the Preclinical Phase meeting the requirements of 21 CFR 58.185, in that it failed, in particular but without limitation, to provide:

- a. the objectives and procedures stated in a Protocol;
- b. the statistical methods employed for analyzing the data;
- c. the test and control articles by name, chemical abstracts number or code number, strength, purity, and composition or other appropriate characteristics;
- d. stability of the test and control articles under the conditions of administration;

- e. the number of animals used, sex, body weight range, source of supply, species, strain and substrain, age, and procedure used for identification;
- f. a description of all circumstances that may have affected the quality or integrity of the data;
- g. a description of the transformations, calculations, or operations performed on the data;
- h. the signed and dated reports of each of the individual scientists or other professionals involved in the study; or
- i. a statement prepared and signed by a quality assurance department as required 21 CFR 58.35(b)(7).

239. Based on the foregoing facts, U-M breached the Second Research Agreement by failing to conduct the Preclinical Phase in compliance with GLP.

240. The Second Research Agreement was governed by Michigan law.

241. Under Michigan law, in every contract for the sale of services, there is an implied warranty that the services will be provided in a diligent and reasonably skillful and workmanlike manner.

242. The degree of skill and care required to satisfy the implied warranty of workmanlike performance is determined by reference to the degree of skill and care customarily expected of similarly situated service providers under like circumstances.

243. U-M holds itself out to the public as a first-class research university possessing excellent facilities and employing highly competent scientific research professionals. As such, the duty of workmanlike performance impliedly undertaken by U-M in the Second Research Agreement was extremely high.

244. U-M breached the implied covenant of workmanlike performance by performing the research contemplated by the Second Research Agreement in a negligent or reckless manner, including by recommending the use of *A. hispida*, rendering the experimental results of the Preclinical Phase useless to EEPI.

245. The Second Research Agreement provided in Section 3.1: “Written program reports shall be provided by [U-M] to [EEPI] periodically and a final report shall be submitted by [U-M] at the conclusion of the Contract Period.”

246. The final report contemplated by Section 3.1 of the Second Research Agreement (the “Final Report”) was a key performance obligation of U-M because it was to form the basis for EEPI’s decision as to whether the results of the Preclinical Phase justified proceeding with the very large expense involved in filing an Investigational New Drug Application with the FDA and ultimately proceeding with clinical trials of the FXY anti-cancer agent, and because a scientifically sound Final Report was necessary to support EEPI’s continued financing of the Project and a potential patent application.

247. U-M further breached the implied covenant of workmanlike performance by delivering a Final Report that misinterpreted the experimental results and provided misleading or unsubstantiated conclusions as to the efficacy of the FXY anti-cancer agent in reducing tumors.

248. The Final Report consisted of a four-page summary accompanied by a PowerPoint presentation consisting of seventy-eight slides (each a “Figure”), most of which reproduced graphs purporting to summarize the results of individual experiments conducted in the course of the Preclinical Phase.

249. The Final Report is cursory at best, provides minimal analysis supporting its conclusions, includes numerous errors, omissions, and misleading statements, including but not limited to the examples provided hereinbelow, and in general does not meet the standard of good and workmanlike service applicable to a first-class research university in Michigan.

250. The Final Report asserts that *A. maritima* is toxic to breast cancer cells but fails to mention that the experimental results on which it relies for this assertion show that at certain concentrations, *A. maritima* causes a proliferation of such cells. A reasonably competent and diligent cancer researcher using ordinary care would not fail to mention such an important adverse finding.



251. The Final Report asserts that the *A. maritima* extract is “very effective at killing cancer tumor stem cells,” but fails to provide data on apoptosis,<sup>3</sup> necrosis,<sup>4</sup> or cell cycle arrest,<sup>5</sup> all of which are necessary to reach such a conclusion. A reasonably competent and diligent cancer researcher using ordinary care would not state such a conclusion in the absence of such data.

252. The Final Report asserts that *A. maritima* was effective against bladder cancer cells, but provides no information concerning the variability observed during the experiments and no indication of how many times they were repeated, both of which are necessary to demonstrate reproducible results. A reasonably competent and diligent cancer researcher using ordinary care would not state such a conclusion in the absence of such information.

253. The Final Report provides results of *in vivo* experiments on bladder and prostate cancer cell lines that were not previously tested by *in vitro* experiments. A reasonably competent and diligent cancer researcher using ordinary care would not conduct *in vivo* experiments on cell lines not previously tested *in vitro*.

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<sup>3</sup> Apoptosis is the death of cells which occurs as a normal and controlled part of an organism’s growth or development.

<sup>4</sup> Necrosis is the death of most or all of the cells in an organ or tissue due to disease, injury, or failure of the blood supply.

<sup>5</sup> Interruption or cessation of cell life cycle occurs when conditions for transition from one stage to another are not met.

254. The Final Report describes *A. maritima* as having a “robust anti-tumor effect” on bladder and prostate cancer cells but provides no data on reproducibility because the test was performed only once. In any case, far from being “robust,” the effect described is statistically insignificant. A reasonably competent and diligent cancer researcher using ordinary care would not make such an assertion based on such data.

255. The Final Report asserts that animals injected with bladder cancer “exhibited statistically significant tumor reduction when treated with *A. maritima* extract,” but the experimental results are unreliable because no information is provided concerning the number of mice in each experimental group or the number of times the experiment was repeated. A reasonably competent and diligent cancer researcher using ordinary care would not make such an assertion based on such data.

256. The Final Report claims “significant inhibition of [prostate] tumor spread to distant organs,” but the experimental data shows a difference in metastatic spread between treated and control mice of less than 10%, which is statistically insignificant. The results as stated are therefore misleading. Moreover, the differing doses used in the relevant experiments and absence of explanation of the statistical methods used render meaningful conclusions impossible. A reasonably competent and diligent cancer researcher using ordinary care would not make such an assertion based on such data.

257. The Final Report describes an experiment on certain breast cancer cells as “one of the most compelling results we have seen with *A. maritima*” in that it “revealed a statistically significant reduction in tumor size in the animals.” This assertion is misleading because although twenty mice were used in the relevant experiments, results were reported for only two of the mice and no statistical information such as mean value or standard deviation was provided. A reasonably competent and diligent cancer researcher using ordinary care would not make such an assertion based on such data.

258. The Final Report provides data supposedly showing that a version of the FXY anti-cancer agent derived from *A. hispidia* was effective against bladder cancer cells but neglects to mention that the experimental data shows an increase in cancer cell proliferation in younger generations of the cell lines studied. A reasonably competent and diligent cancer researcher using ordinary care would not fail to mention such an important adverse finding.

259. The Final Report describes an experiment purportedly intended to evaluate the toxicology of the FXY anti-cancer agent but finds merely that “all animals looked healthy upon necropsy.” It is misleading to describe this assertion as a “toxicology” result. A reasonably competent and diligent cancer researcher using ordinary care would have provided blood chemistry and pharmacokinetic/

pharmacodynamic analyses to determine the toxicological effects of the experiments on the animals used.

260. In general, the Final Report fails to provide information concerning the statistical methods used to analyze results, the reproducibility of results, or the number of animals actually used in *in vivo* experiments in relation to the number of animals whose results are reflected in the figures. The Final Report also relied on statistically insignificant data to report purportedly dramatic positive results. As such, the results reported in the Final Report cannot be relied upon to draw any conclusions as to whether or not the FXY anti-cancer agent has any relevant effect on cancerous tumors.

261. The Final Report concludes: “The organic extract of *A. maritima* is extremely effective in killing all tumor models tested, whether in cell culture or in animals.” Given the flawed scientific methods used, the data generated in the Preclinical Phase cannot be relied upon to support any definite scientific conclusion one way or the other as to the efficacy or safety of the FXY anti-cancer agent. A reasonably competent and diligent cancer researcher using ordinary care would not make such an assertion based on such data.

262. The Final Report concludes that *A. hispidia* has the same efficacy as *A. maritima*. In fact, to the extent the flawed experimental data can support any

conclusion at all, it is that extracts of *A. hispida* are greatly inferior to *A. maritima* as anti-cancer agents.

263. The Final Report concludes that extracts of both *A. hispida* and *A. maritima* “appear to kill at the level of the cancer stem cell.” This conclusion is misleading and is not supported by the flawed data given in the Final Report.

264. The Final Report concludes that “ambrosin in its pure form is a very active anti-cancer agent in cell-culture and in actual human [breast cancer] tumors transplanted into culture dishes.” This conclusion is misleading and is not supported by the flawed data given in the Final Report.

265. The Final Report concludes that “all experiments indicate that ambrosin does exhibit efficacy and does not appear toxic to mice.” In fact, the Final Report does not present a single experiment in which a statistically significant anti-tumor effect is observed in any of the cancer models treated with purified ambrosin, whether from *A. maritima* or *A. hispida*, nor does it contain any scientific data concerning ambrosin’s toxicology in mice.

266. The Final Report concludes that “[t]he molecular target of ambrosin and its mechanism of action are nearly validated.” In fact, no conclusions can be drawn as to the mechanism of action of ambrosin as an anti-cancer agent because the data generated in the Preclinical Phase is scientifically inadequate to support a conclusion one way or the other as to the efficacy of ambrosin as anti-cancer agent.

267. A reasonably competent and diligent researcher using ordinary care would not reach the foregoing conclusions based on the data presented.

268. For the foregoing reasons, U-M's performance under the Second Research Agreement breached the implied warranty of diligent, skillful, and workmanlike performance of services.

269. U-M's breach of the implied warranty of workmanlike performance has caused damage to EEPI.

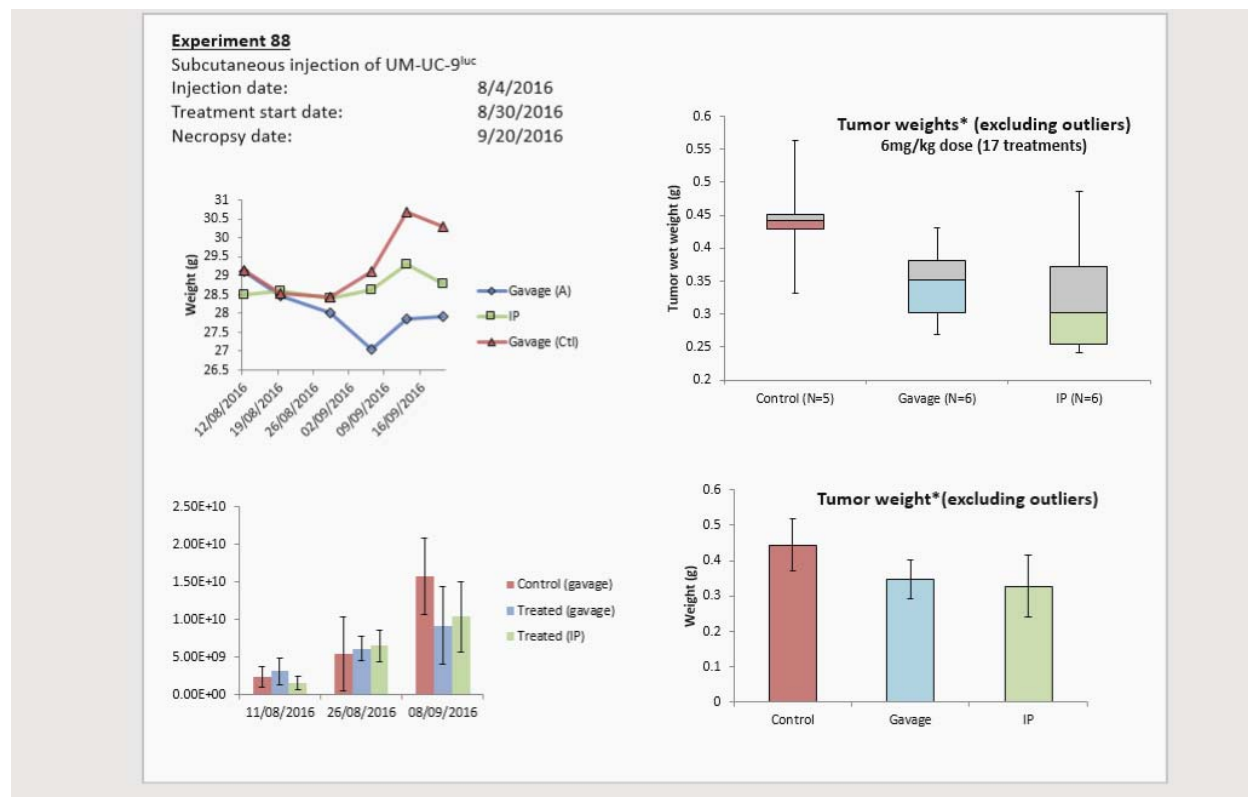
270. There is also implied in every contract governed by Michigan law a covenant that each party will perform in good faith and fair dealing with respect to matters over which it has discretion. As detailed below, Defendants also breached this covenant under the Second Research Agreement.

271. In August and September 2016, as a part of the Preclinical Phase, Ms. El-Sawy ran an experiment ("Experiment 88") to test the effect of *A. maritima* on bladder cancer.

272. Experiment 88 consisted of injecting a mouse with bladder cancer cells to cause it to form a cancerous tumor and then treating the tumor with ambrosin from *A. maritima*.

273. Experiment 88 was concluded while Ms. El-Sawy was visiting Egypt. She therefore asked Day to e-mail the results to her. On September 23, 2016, Day e-mailed to Ms. El-Sawy a PowerPoint slide ("Slide 88") entitled "Experiment 88,"

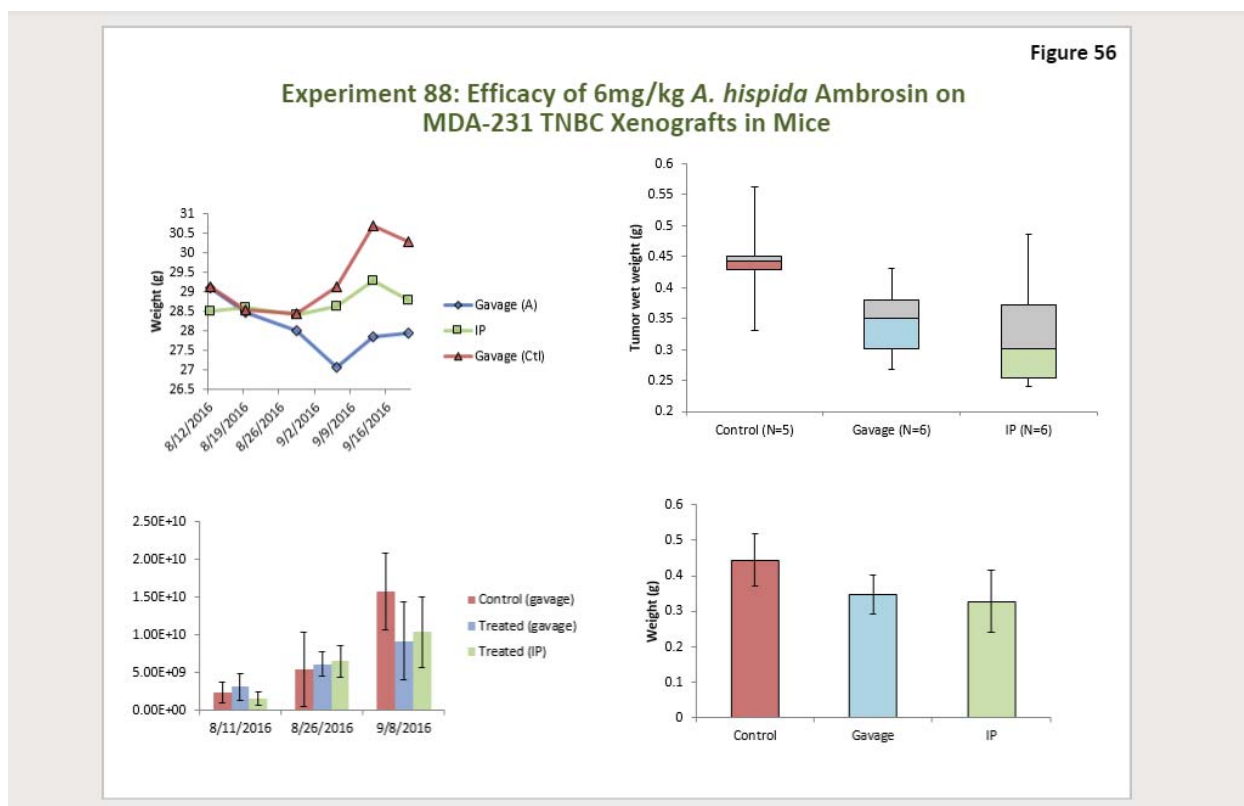
showing the results of the experiment Ms. El-Sawy had run. A true copy of Slide 88 is provided below.



274. Slide 88 shows that Experiment 88 was performed using a cell culture of U-M-UC-9, a strain of bladder cancer cells developed by U-M. Experiment 88 was conducted between August 4, 2016, and September 20, 2016. It depicts the results obtained with three groups of mice: one in which ambrosin was administered by gavage (i.e., through an oral feeding tube), one in which ambrosin was administered by intra-peritoneal (“IP”) injection, and one in which an unidentified control article was administered by gavage.

275. The results shown in Slide 88 indicate that the group treated with ambrosin by gavage showed a slightly greater improvement than the group treated with ambrosin by IP injection, while the control group suffered an increase in tumor weight. In fact, the apparent difference between the gavage and IP group is too small to be of statistical significance.

276. The Final Report also presented a slide purporting to depict the results of an experiment identified as “Experiment 88.” A true copy of the Final Report slide (identified herein as “Figure 56”) is provided below.



277. Figure 56 is obviously identical to Slide 88, *except* that it is entitled “Experiment 88: Efficacy of 6mg/kg *A. hispidus* Ambrosin on MDA-231 TNBC



Xenografts in Mice.” (emphasis added.) “MDA-231 TNBC” refers to a strain of breast cancer cells, not to the bladder cancer that was the true subject of Experiment 88 as performed by Layla El-Sawy. FR 88 also asserts that Experiment 88 was carried out using ambrosin from *A. hispida*, while Experiment 88 was in fact performed using ambrosin from *A. maritima*.

278. Upon information and belief, Day was motivated to promote *A. hispida* in order to cause EEPI to pay his expenses charged to the Project for extravagant and unnecessary travel throughout the United States.

279. Upon information and belief, U-M and Day intentionally falsified the results of Experiment 88 in the Final report by copying Slide 56, inserting into it a deceptive title intended to create the false impression that *A. hispida* was effective to reduce breast cancer tumors, presenting it as Slide 56 in the Final Report, and asserting in the Final Report text that it demonstrated that *A. hispida* was effective to reduce breast cancer tumors.

280. Under the Second Research Contract the conduct of the Project and the preparation of the Final Report were committed to U-M’s and Day’s discretion.

281. By presenting false results for Experiment 88 in Slide 56 and in the text of the Final Report U-M and Day breached the implied covenant of good faith.

282. U-M's and Day's breach of the covenant of good faith raises doubt as to the validity of the entire Final Report and of the scientific research on which it is based, rendering the Final Report useless for the purposes for which it was intended.

283. Without a scientifically valid Final Report, the Project has no practical or economic value for EEPI, because an invalid Final Report cannot be used to support further research, obtain financing, or support applications for a patent of the FXY anti-cancer agent.

284. U-M's and Day's breach of the implied covenant of good faith has caused damage to EEPI.

285. EEPI performed all of its obligations under the Second Research Agreement.

286. EEPI has suffered damage caused by U-M's breaches of contract.

**COUNT VIII**  
**FRAUD/MISREPRESENTATION**  
**(By EEPI Against U-M and Day)**

287. Plaintiffs reallege and incorporate all proceeding paragraphs as if fully restated herein.

288. The Second Research Agreement contemplated a study of a potential anti-cancer agent derived from *A. maritima*. The primary test article intended to be used in the *in vitro* and *in vivo* experiments was an extract of *A. maritima* known as "ambrosin."

289. In the midst of the Preclinical Study, Day announced that the supplies of Egyptian *A. maritima* being provided by EEPI were “running short,” and requested EEPI’s approval to explore potential sources of ambrosin from other species of the Ambrosia family apart from *A. maritima*.

290. Upon information and belief, the supplies of *A. maritima* EEPI supplied to U-M and Day were in fact more than sufficient for the purposes of the Preclinical Phase.

291. Upon information and belief, Day falsely asserted that there was a need to explore other sources of ambrosin apart from *A. maritima* because he wished to travel to various parts of the United States at EEPI’s expense.

292. Day did in fact make numerous trips to various parts of the United States at EEPI’s expense, including three trips Florida, for which he charged extravagant and unnecessary sums to the Project.

293. EEPI, through counsel, repeatedly requested that U-M audit Day’s trips to determine whether the expenses he charged for them were proper. These requests were made to Dr. Bloom, who made personal assurances the audits would be made.

294. EEPI was never made aware that such an audit was undertaken. Upon information and belief, this is because U-M did not audit Day as promised.

295. Over the course of his trips to Florida, Day collected samples of a member of the *Ambrosia* family called *A. hispida* that was endemic to southern

Florida. He also collected samples of 6 other *Ambrosia* species from various locations around the southern United States, again charging the Project for his lavish and unnecessary expenses for travel, meals, and lodging.

296. Day incorporated into the Project a costly series of experiments purportedly to determine which of the various *Ambrosia* species he had collected would provide a suitable source of ambrosin.

297. Ultimately, Day recommended that a member of the *Ambrosia* family called *A. hispida* that was endemic to southern Florida should be used in the Project.

298. In reliance on Day's supposedly expert advice that *A. hispida* would provide a suitable substitute for *A. maritima* and would not affect the scientific validity of the Preclinical Phase, EEPI agreed that U-M could use *A. hispida*.

299. In fact, changing the source of the test article in the middle of the study was a grave scientific error that could be considered to invalidate any experimental results based on the substitute compound. As Day was aware, a researcher faced with a shortage of the supply of the test article would need to find a way to increase the supply, suspending the study if necessary to do so. As Day was also aware, any other action, including substituting the test article with an inappropriate replacement, would potentially invalidate the entire study and render any time or work put into it useless.

300. There was a plentiful and available supply of *A. maritima* in Egypt which EEPI could have provided to Day and U-M upon request. No such request was made.

301. If the supply of *A. maritima* could not be increased to the level required for the Preclinical Phase, then a reasonably competent researcher would not have substituted *A. maritima* with of *A. hispida* before first performing direct head-to-head studies to confirm that ambrosin from both species had the same cytotoxic effect. U-M and Day did not perform any such studies before performing experiments using *A. hispida*.

302. To the extent that the scientific results of the Preclinical Phase can be taken to have generated any scientifically reliable results, they show that *A. hispida* is greatly inferior to *A. maritima* in its cytotoxic effects.

303. U-M and Day expressly and impliedly undertook to exercise and owed a duty to EEPI to exercise reasonable care in providing advice to EEPI regarding the design, planning, conduct, and conclusions of the Preclinical Phase, including the use of *A. hispida*, and the advisability of investing money in the Preclinical Phase using the techniques and methods being employed by U-M and Day, that is, without employing GLP.

304. U-M and Day breached that duty by falsely promising, representing, and assuring EEPI that the techniques and methods being employed by U-M and

Day, including the use of *A. hispida*, were scientifically sound and that their results justified EEPI's investment of money in the Preclinical Phase using such techniques and methods.

305. Day's assertion that *A. hispida* would provide a suitable substitute for *A. maritima* and would not affect the scientific validity of the Preclinical Phase was a material misrepresentation of fact.

306. Day's assertion that *A. hispida* would provide a suitable substitute for *A. maritima* and would not affect the scientific validity of the Preclinical Phase was false.

307. Day's assertion that *A. hispida* would provide a suitable substitute for *A. maritima* and would not affect the scientific validity of the Preclinical Phase was made with the knowledge that it was false, or was made recklessly, without knowledge of its truth, and as a positive assertion.

308. Day's assertion that *A. hispida* would provide a suitable substitute for *A. maritima* and would not affect the scientific validity of the Preclinical Phase was made with the intention that EEPI would act upon it by permitting Day to use *A. hispida* in the remainder of the Preclinical Phase.

309. EEPI justifiably relied upon U-M and Day to exercise ordinary and reasonable care in providing advice to EEPI concerning the advisability of investing money in the Preclinical Phase using such techniques and methods.

310. Despite their duty of care owed to EEPI, U-M and Day failed and neglected to exercise reasonable care in advising EEPI to invest money in the Preclinical Phase inasmuch as the techniques and methods employed by U-M in designing, planning, conducting, and analyzing the results of the Preclinical Phase were scientifically unsound and could not lead to a Final Report that would meet EEPI's objectives.

311. EEPI relied upon U-M's and Day's promises, representations and assurances to its substantial detriment including, but not limited to, the expenditure of more than \$2,300,000 on a scientific study that never had any possibility of achieving usable results.

312. By virtue of U-M's and Day's willful, wanton, malicious and bad faith conduct, EEPI is entitled recover exemplary damages.

313. As a direct, natural, proximate and foreseeable consequence of the foregoing, EEPI has suffered damages for which it is entitled to recover, including, but not limited to compensatory damages, consequential damages, exemplary damages, interest, costs, and attorney fees.

### **RELIEF REQUESTED**

WHEREFORE, EEPI and Layla El-Sawy demand that judgment be entered against Defendants as follows:

- A. Direct damages in an amount to be proven at trial but reasonably believed to be in excess of \$5,000,000, plus interest, costs, and attorneys' fees;
- B. Consequential damages in an amount to be proven at trial but reasonably believed to be in excess of \$1,000,000;
- C. Punitive and/or exemplary damages in an amount to be proven at trial;
- D. A declaration of the rights of EEPI, U-M, and Day under the Operative Contracts at issue in this matter;
- E. Interest, costs, and attorneys' fees; and
- F. Such other and further relief as the Court shall find to be warranted and appropriate.

Respectfully submitted,

**THE MILLER LAW FIRM, P.C.**

/s/ E. Powell Miller

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*Attorneys for Plaintiffs*

Dated: December 30, 2020



**JURY DEMAND**

Plaintiffs Layla Fakhr El-Din El-Sawy and Egyptian European Pharmaceutical Industry, by and through their attorneys, The Miller Law Firm, P.C., hereby demand a trial by jury on all issues so triable in the above referenced matter.

Respectfully submitted,

**THE MILLER LAW FIRM, P.C.**

/s/ E. Powell Miller

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Dated: December 30, 2020